REMARKS

Claims 1, 3-6, 8-12, 18-26, 28-37, and 39-40 are pending in the application. Claims 1-12 and 18-40 stand rejected. Claims 2, 7, 13-17, 27, and 38 have been canceled.

In accordance with 37 C.F.R. 1.136(a), a one month extension of time is submitted herewith to extend the due date of the response to the Office Action dated August 26, 2004, for the above-identified patent application from November 26, 2004, through and including December 26, 2004. In accordance with 37 C.F.R. 1.17(a)(3), authorization to charge a deposit account in the amount of $120.00 to cover this extension of time request also is submitted herewith.

The rejection of Claims 1-5, 8-12, 23-26, 28-37, and 39-40 under 35 U.S.C. § 103 as being unpatentable over Baggiolini et al. (US Patent No. 5,087,619) and Abdaimi et al. (Cancer Research, 1999, 59:3325-3328) is respectfully traversed.

Applicants note the following with respect to the law of obviousness. As explained by the Federal Circuit, "to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant." In re Kotzab, 54 USPQ2d 1308, 1316 (Fed. Cir. 2000). The required teaching, suggestion and incentive supporting the Examiner's combination is absent here. Neither Baggiolini et al. nor Abdaimi et al. teach or suggest the claimed combination. Furthermore, in contrast to the assertion within the Office Action, Applicant respectfully submits that it would not be obvious to one skilled in the art to combine Baggiolini et al. with Abdaimi et al. because there is no motivation to combine these references suggested in the art. The Examiner has not pointed to any prior art that teaches or suggests combining the disclosures.

As the Federal Circuit has recognized, obviousness is not established merely by combining references having different individual elements of pending claims. Ex parte Levengood, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). MPEP 2143.01. Rather, there must be some suggestion, outside of Applicant's disclosure, in the prior art to combine such references, and a reasonable expectation of success must be both found in the prior art, and not based on Applicant's disclosure. In re Vaeck, 20 U.S.P.Q.2d 1436 (Fed. Cir. 1991). In the present case, neither a suggestion nor motivation to combine the prior art disclosures, nor any reasonable expectation of success has been shown. Specifically, the Examiner has

not pointed to any prior art that teaches or suggests a reasonable expectation of success or motivation in combining the references.

Furthermore, "[i]t is impermissible . . . to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." In re Wesslau, 147 USPQ 391, 393 (CCPA 1965). See also, Smithkline Diagnostics, Inc. v. Helena Laboratories, Corp., 8 USPQ2d 1468, 1475 (Fed. Cir. 1988) ("claims, entire prior art, and prior art patents must be read 'as a whole'"). If art "teaches away" from a claimed invention, such a teaching supports the nonobviousness of the invention. U.S. v. Adams, 148 USPQ 479 (1966); Gillette Co. v. S.C. Johnson & Son, Inc., 16 USPQ2d 1923, 1927 (Fed. Cir. 1990). Further, it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. The present Section 103 rejection is apparently based on a combination of teachings selected from multiple patents in an attempt to arrive at the claimed invention.

Since there is no teaching, suggestion, or motivation in the cited references for the claimed combination recited in Claims 1-5, 8-12, 23-26, 28-37 and 39-40, the Section 103 rejection of Claims 1-5, 8-12, 23-26, 28-37 and 39-40 appears to be based on an impermissible hindsight reconstruction in which isolated disclosures have been picked and chosen in an attempt to deprecate the present invention. Of course, such a combination is impermissible.

In light of the above standard of obviousness and the reasons set forth below, it is respectfully submitted that the cited art does not support the present rejection of the claims.

Claim 1 recites a "method of treating SCC 2/88, a canine squamous carcinoma cell line, for cancer, comprising the step of feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog selected from the group consisting of $1\alpha,25\text{-}(OH)_2D_3$, $1\alpha,25\text{-}(OH)_2\text{-}16\text{-ene-}23\text{-yne-}D_3$ and $1\alpha,25\text{-}(OH)_2\text{-}22,24\text{-diene-}24,26,27\text{-trihomo-}D_3$ and stereoisomers thereof."

Claim 26 recites a method of "providing a therapeutic agent to a pet, wherein the agent comprises a vitamin D analog selected from the group consisting of $1\alpha,25$-

$(OH)_2D_3$, 1α,25-$(OH)_2$-16-ene-23-yne-D_3, and 1α,25-$(OH)_2$-22,24-diene-24,26,27-trihomo-D_3 and stereoisomers thereof, said method comprising providing a pet food including a proteinaceous component, a farinaceous component, and the agent, and feeding the pet food to a pet."

Claim 34 recites a method of "administering a pharmaceutical agent to a pet, wherein the agent comprises a vitamin D analog selected from the group consisting of 1α,25-$(OH)_2D_3$, 1α,25-$(OH)_2$-16-ene-23-yne-D_3, and 1α,25-$(OH)_2$-22,24-diene-24,26,27-trihomo-D_3 and stereoisomers thereof, said method comprising providing a pet food including a proteinaceous component, a farinaceous component, and the agent, and feeding the pet food to a pet."

Baggiolini et al. teach a method of treating leukemia and basal cell carcinoma in a warm-blooded animal, i.e., a human, comprising administering an effective amount of a Vitamin D analog. Baggiolini et al. fail to teach or suggest a method as recited in Claim 1. The dosage is administered orally or topically, depending on the disease to be treated. There is no mention within Baggiolini of feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog selected from the group consisting of 1α,25-$(OH)_2D_3$, 1α,25-$(OH)_2$-16-ene-23-yne-D_3 and 1α,25-$(OH)_2$-22,24-diene-24,26,27-trihomo-D_3 and stereoisomers thereof.

Abdaimi et al. teach the use of EB 1089 as an antiproliferative and prodifferentiative agent. Specifically, Adaimi et al describe a study that was conducted on nude mice implanted with a human epithelial cancer previously shown to produce high levels of PTHRP *in vitro*. The strategy employed was to use a continuous infusion of EB1089, which does not produce calcium elevation in control non-tumor-bearing animals. In accordance with this strategy, a pump was implanted adjacent the tumor to deliver a high concentration of the analogue to the tumor site. Certainly there is no indication or suggestion within Abdaimi et al regarding feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog selected from the group consisting of 1α,25-$(OH)_2D_3$, 1α,25-$(OH)_2$-16-ene-23-yne-D_3 and 1α,25-$(OH)_2$-22,24-diene-24,26,27-trihomo-D_3 and stereoisomers thereof. Abdaimi et al. do not teach nor suggest a dog food comprising a proteinaceous component, a farinaceous component and a therapeutic agent comprising a vitamin D analog. Abdaimi et al clearly dictate that a continuous dosage be provided to the specific site so that elevated levels of calcium are not produced. This certainly teaches away from feeding a dog a dog food

containing an amount of a specific compound. Accordingly, Applicant respectfully submits that the method recited in the independent claims involves more than "routine practice for providing such medication to animals" as explained in the August 26, 2004 Office on page 4. Applicant respectfully requests that the Examiner provide a specific reference indicating a reasonable expectation of success from feeding a dog a dog food containing the compounds recited in the independent claims.

Applicant respectfully submits that Baggiolini et al. and Abdaimi et al. do not teach nor suggest the methods recited in independent Claims 1, 26, and 34. Neither Baggiolini et al. nor Abdaimi et al. teach or suggest a method of treating SCC 2/88, a canine squamous carcinoma cell line, for cancer, comprising the step of feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog selected from the group consisting of 1α,25-$(OH)_2D_3$, 1α,25-$(OH)_2$-16-ene-23-yne-D_3 and 1α,25-$(OH)_2$-22,24-diene-24,26,27-trihomo-D_3 and stereoisomers thereof. Specifically, neither Baggiolini et al. nor Abdaimi et al. teach or suggest feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog selected from the group consisting of 1α,25-$(OH)_2D_3$, 1α,25-$(OH)_2$-16-ene-23-yne-D_3 and 1α,25-$(OH)_2$-22,24-diene-24,26,27-trihomo-D_3 and stereoisomers thereof. There is no motivation shown or discussed within either reference provided by the Examiner to combine the teachings of Baggiolini et al and Abdaimi et al. In addition, there is no indication within either reference indicating a reasonable expectation of success with the method recited in Claim 1. This is due, at least in part, to the fact that even if the references are combined, they still do not teach or suggest the methods recited in Claims 1, 26, and 34.

For the reasons set forth above, Applicant submits that Claims 1, 26, and 34 are patentable over Baggiolini et al. and Abdaimi et al.

Claims 3-5, 8-12, and 23-25 depend, directly or indirectly, from independent Claim 1. When the recitations of Claims 3-5, 8-12 and 23-25 are considered in combination with the recitations of Claim 1, Applicant submits that dependent Claims 3-5, 8-12 and 23-25 likewise are patentable. Claims 28-33 depend from independent Claim 26. When the recitations of Claims 28-33 are considered in combination with the recitations of Claim 26, Applicant submits that dependent Claims 28-33 likewise are patentable. Claims 35-37 and 39-40 depend, directly or indirectly, from independent Claim 34. When the recitations of

Claims 35-37 and 39-40 are considered in combination with the recitations of Claim 34, Applicant submits that dependent Claims 35-37 and 39-40 likewise are patentable.

For at least the reasons set forth above, Applicant respectfully requests that the Section 103 rejections of Claims 1-5, 8-12, 23-26, 28-37, and 39-40 are overcome and should be withdrawn.

The rejection of Claims 6 and 18-22 as being unpatentable under 35 U.S.C. § 103 over Baggiolini et al. and Abdaimi et al. as applied to Claims 1-5 and 8-12 and in view of Katzung (Basic and Clinical Pharmacology, p.661-663, 838, 841, 830-832) and Hardman et al. (Goodman and Gilman's The Pharmacological Basis of Therapeutics, P. 539) is respectfully traversed.

Claims 6 and 18-22 depend from Claim 1. As indicated above, there is insufficient motivation to combine Baggiolini et al with Abdaimi et al. and there is no reasonable expectation of success if these references are combined. Katzung teaches that hypercalcemia causes central nervous system depression, including coma and is potentially lethal. Its major causes (other than thiazide therapy) are hyperparathyroidism and cancer with or without bone metastases. Further Katzung teaches that less common causes are hypervitaminosis D, sarcoidosis, thyrotoxicosis, mil-alkali syndrome, adrenal insufficiency and immobilations. Hardman et al. is a page from a text book indicating that pain is associated with cancer.

Claim 1 recites a "method of treating SCC 2/88, a canine squamous carcinoma cell line, for cancer, comprising the step of feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog selected from the group consisting of 1α,25-$(OH)_2D_3$, 1α,25-$(OH)_2$-16-ene-23-yne-D_3 and 1α,25-$(OH)_2$-22,24-diene-24,26,27-trihomo-D_3 and stereoisomers thereof."

Applicant respectfully submits that none of Baggiolini et al., Abdaimi et al., Katzung and Hardman et al. teach or suggest a method as recited in Claim 1. Specifically, none of Baggiolini et al., Abdaimi et al., Katzung, and Hardman et al. teach or suggest feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog selected from the group consisting of 1α,25-$(OH)_2D_3$, 1α,25-$(OH)_2$-16-ene-23-yne-D_3 and 1α,25-$(OH)_2$-22,24-diene-24,26,27-trihomo-D_3 and stereoisomers thereof. Rather, Baggiolini et al. teach a method of treating leukemia and basal cell carcinoma in a warm-blooded animal comprising administering an

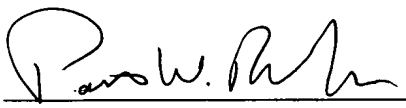
effective amount of a Vitamin D analog; Abdaimi et al. teach the use of EB 1089 as an antiproliferative and prodifferentiative agent; Katzung teaches that hypercalcemia causes central nervous system depression, including coma and is potentially lethal. Its major causes (other than thiazide therapy) are hyperparathyroidism and cancer with or without bone metastases; and Hardman et al. is a page from a text book indicating that pain is associated with cancer. For the reasons set forth above, Applicant submits that Claim 1 is patentable over Baggiolini et al., Abdaimi et al., Katzung, and Hardman et al.

In addition, Katzung appears to be a non-analogous reference since Katzung does not relate to a method of treating SCC 2/88, a canine squamous carcinoma cell line, for cancer, comprising the step of feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog, as recited in Claim 1. Accordingly, Claim 1 is submitted to be patentable over Baggiolini et al. and Abdaimi et al. in view of Katzung and Hardman et al.

When the recitations of Claims 6 and 18-22 are considered in combination with the recitations of Claim 1, Applicant submits that dependent Claims 6 and 18-22 likewise are patentable.

In view of the foregoing amendments and remarks, all the claims now active in this application are believed to be in condition for allowance. Reconsideration and favorable action is respectfully solicited.

Respectfully submitted,



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